means for determining at least one of a clearance and a dialysance during a dialysis treatment, at the at least one of the blood flow rate Qb, the dialysis fluid flow rate Qd, and the ultrafiltration rate Qf determined by the first device, wherein the means for determining at least one of a clearance and a dialysance is a computer unit which determines at least one of the clearance and the dialysance at the at least one of a blood flow rate Qb(t), a dialysis fluid flow rate Qd(t), and an ultrafiltration rate Qf(t), on the basis of at least one of the clearance and a dialysance established at the at least one of a predetermined blood flow rate Qb, a predetermined dialysis fluid flow rate Qd, and a predetermined ultrafiltration rate Qf.

Please cancel claim 8 without prejudice.

REMARKS

I. Introduction

With the withdrawal of claims 1 to 6 as being drawn to a non-elected invention, and with the withdrawal of claim 8 herein, claims 7 and 9 to 13 are pending in the present application. In view of the foregoing amendments and the following remarks, it is respectfully submitted that all of the presently pending claims are allowable, and reconsideration is respectfully requested.

Applicants note with appreciation the acknowledgment of the claim for foreign priority and the indication that all certified copies of the priority documents have been received.

Applicants notes that the Office Action states that the previously filed Information Disclosure Statement, PTO-1449 paper and cited references were not considered because it failed to comply with 37 C.F.R. 1.98(a)(2). Applicants file herewith another copy of the Information Disclosure Statement along with copies of all listed references, and respectfully requests that the Examiner consider same.

II. Objections to Drawings

The Office Action Summary indicates at paragraph 10 that the drawings filed on June 22, 2000 are objected to by the Examiner. However, the Office Action does not provide any reasons for such objection. Therefore,

Applicants respectfully request that the Examiner provide a reason for such objection, or else withdraw the objection.

III. Objection to the Oath/Declaration

The oath or declaration was deemed to be defective under 37 C.F.R. 1.67(a) because it contains changes that have not been initialed. Please find enclosed a new oath/declaration complying with 37 C.F.R. 1.67(a). It is respectfully submitted that the objection to the oath/declaration has been obviated, and withdrawal of this objection is therefore respectfully requested.

IV. Objection to the Specification

The Specification was objected to as failing to provide proper antecedent basis for the claimed subject matter. Specifically, the Office Action states that "the claim limitation 'rate determination means' of claim 1 is not supported by the specification." Office Action at page 3. In addition, the Office Action states that "it is unclear if applicants's intent is to invoke 35 U.S.C. 112, sixth paragraph by the recitation of [rate determining means]." Office Action at page 4.

As an initial matter, it is assumed by the Applicants that the Examiner's reference to claim 1 is in error and that the objection is in fact directed to the recitation of "rate determining means" in claim 7. In addition, the Specification states at page 9, lines 17 to 26 that:

> "[t]he measured values of conductivity sensors 16, 17 are supplied over signal lines 18, 19 to a device 21 which has a computer unit 22 for determining clearance C and/or dialysance D. Computer unit 22 is, for example, a microprocessor of the type known in the art. Via a data line 23 leading to control unit 13, device 21, as part of determining the clearance and the dialysance, detects the delivery rates of blood pump 6, dialysis fluid pump 12, and/or ultrafiltration pump 29, which thereby specify the blood flow rate Qb, dialysis fluid rate Qd, and/or the ultrafiltration rate." (emphasis added).

Thus, Applicants respectfully maintain that the Specification makes clear, e.g., explicitly states, that it is the device 21 that is responsible for detecting the blood and

dialysis fluid flow rate and/or the ultrafiltration rate. Furthermore, with respect to the Office Action's comment concerning the invocation of 35 U.S.C. 112, sixth paragraph, it is noted that claim 7 has been amended to delete the term "rate determination means" and to instead recite "a device", as described in the specification at page 9, lines 17 to 26.

It is respectfully submitted that the objections to the Specification have been obviated, and withdrawal of these objections are therefore respectfully requested.

V. Rejection of Claim 7 Under 35 U.S.C. § 112

Claim 7 was rejected under 35 U.S.C. § 112, second paragraph as indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The Office Action contends that "it is unclear as to what structure performs the function of determining ... the blood and dialysis fluid flow rates and/or the ultrafiltration rate [and whether it is] the control unit (13) which is disclosed to preselect the flow for the pumps or the 'device' (21) which actually calculates values based on the rates [since] the control unit (13) is disclosed only to establish the preselected flow rates [and] is not disclosed as a 'determining' means." Office Action at pp. 4 to 5.

The second paragraph of 35 U.S.C. § 112 merely requires that the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. See M.P.E.P. § 2173.02. It is respectfully submitted that claim 7, which has been amended herein to recite "a device for determining at least one of a blood flow rate Qb through the blood chamber, a dialysis fluid flow rate Qd through the dialysis fluid chamber, and an ultrafiltration rate Qf", satisfies this requirement. Furthermore, and as more fully described above, Applicants respectfully maintain that the Specification makes clear, e.g., explicitly states, that it is the device 21 that is responsible for detecting the blood and dialysis fluid flow rate and/or the ultrafiltration rate. Furthermore, with respect to the Office Action's comment concerning the invocation of 35 U.S.C. 112, sixth paragraph, it is noted that claim 7 has been amended to delete the term "rate determination means" and to instead recite "a device", as described in the specification at page 9, lines 17 to 26.

In view of the foregoing, it is respectfully submitted that claim 7 fully complies with the requirements of 35 U.S.C. § 112, and withdrawal of this rejection is therefore respectfully requested.

VI. Rejection of Claims 7, 8, 12 and 13 Under 35 U.S.C. § 102(e)

Claims 7, 8, 12 and 13 were rejected under 35 U.S.C. 102(e) as anticipated by U.S. Patent No. 5,744,031 ("Bene"). Applicants respectfully submit that Bene does not anticipate the present claims for the following reasons.

Claim 7 relates to a dialysis machine. Claim 7 recites that the dialysis machine includes that includes a dialyzer and a semipermeable membrane dividing the dialyzer into a blood chamber and a dialysis fluid chamber, the blood chamber having an inlet and an outlet, and the dialysis fluid chamber having an inlet and an outlet. Claim 7 also recites that the dialysis machine includes an arterial blood line connected to the inlet of the blood chamber, and a venous blood line connected to the outlet of the blood chamber. Claim 7 also recites that the dialysis machine includes a dialysis fluid inlet line connected to the inlet of the dialysis fluid chamber, and a dialysis fluid outlet line connected to the outlet of the dialysis fluid chamber. Claim 7 also recites that the dialysis machine includes a device for determining at least one of a blood flow rate Qb through the blood chamber, a dialysis fluid flow rate Qd through the dialysis fluid chamber, and an ultrafiltration rate Qf. In addition, claim 7 recites that the dialysis machine includes means for determining at least one of a clearance and a dialysance during a dialysis treatment, at the at least one of the blood flow rate Qb, the dialysis fluid flow rate Qd, and the ultrafiltration rate Qf determined by the first device.

Bene purports to relate to an artificial kidney that includes measurement structure for measuring at least one physical characteristic of a fresh dialysis liquid and of used liquid. According to Bene, the measurement structure are disposed in a line portion common to a branch circuit to the feeder line of fresh dialysis liquid and to a branch circuit to the discharge line for the used liquid. Bene states that an occluding structure permits the liquid to circulate exclusively in one or the other branch circuit, and that, due to this arrangement, it is possible to obtain the value of the physical characteristics of a patient's blood by calculation as frequently

as desired, and to adjust the operation of the kidney permanently to a therapeutic objective set by the physician.

The Office Action contends that "Bene discloses a dialysis system comprising a dialyzer (1) divided by a semipermeable membrane (4) into a blood chamber (2) and a dialysis chamber (3) [and that the] blood chamber has an inlet connected to an arterial blood line (5) and an outlet connected to a venous blood line (7)." Office Action at p. 6. The Office Action also contends that "[s]ince the claim is open-ended (i.e. "comprising"), the venous line is seen to be connected to the blood outlet regardless of the intervening bubble trap [and since] the claim does not require that the venous line be "directly connected" to the outlet [ ] this limitation is met." Office Action at p. 6. The Office Action also states that "[t]he dialysis chamber has an inlet connected to a dialysis fluid inlet line (13) and an outlet connected to a dialysis fluid outlet line (29) [, a] blood pump (6) is connected to the arterial, a first dialysis fluid pump (15) is connected to the dialysis inlet line and a second dialysis fluid pump (22) is connected to the dialysis fluid outlet line [and] flow meters (24/25) measure the inflow and outflow rates of the dialysis fluid." Office Action at p. 6. The Office Action further contends that "[a]s best can be understood by the examiner based on the specification as filed, either or both of the flow meters is equivalent to applicant's 'rate determining means' since they measure or determine the dialysis fluid flow rates." Office Action at p. 6. The Office Action further contends that "Bene ... discloses that the computing and control unit (26) can calculate the dialysance of the apparatus during the treatment session based on blood flow rate and/or dialysis liquid flow rate values sent to the control unit (see figure 1 & col. 4, line 33-col.6, line 51)." Office Action at pp. 6 to 7.

It is respectfully submitted that Bene fails to disclose, or even suggest, that a means for determining at least one of a clearance and a dialysance is a computer unit which determines at least one of the clearance and the dialysance at at least one of a blood flow rate Qb(t), a dialysis fluid flow rate Qd(t), and an ultrafiltration rate Qf(t), on the basis of at least one of the clearance and the dialysance established at the at least one of a predetermined blood flow rate Qb, a predetermined dialysis fluid flow rate Qd, and a predetermined ultrafiltration rate Qf as recited in amended claim 7. In contrast, Bene describes that "the extraction pump 21 is regulated by a control unit 26, according to the comparison of a desired

rate of ultrafiltration WL/T and the measured rate of ultrafiltration." Col. 5, lines 14 to 17. Bene also describes that "the signals delivered by the sensors 27 are supplied to the computing and control unit 26 which controls the artificial kidney according to the parameters which it calculates, such as certain characteristic values of the blood (the concentration of ionized substances, of bicarbonate for example) as well as the performance of the artificial kidney (dialysance, clearance for a given substance) and according to the data which are supplied to it by an operator prior to the treatment session, such as the duration T of the session, the flow rates of the blood QB and of the dialysis liquid QD, the desired loss of weight WL, the desired concentration [A], [B], [C] of electrolytes A, B, C in the blood, and in particular, the desired clearance of urea KUR." Col. 3, line 65 to col. 6, line 11 (emphasis added). Furthermore, Bene states that "[b]efore the start of a treatment session, an operator provides the computing and control unit 26 with the necessary data for controlling the artificial kidney, that is to say, the composition of the dialysis liquid with electrolytes A and B, the delivery rate QB of the circulating pump 6 for the blood, the delivery rate QD of the circulating pump 15 for the dialysis liquid, the desired loss of weight WL and the duration set beforehand for the treatment session T." Col. 6, lines 15 to 22 (emphasis added). Thus, Bene does not disclose a computer unit which determines at least one of the clearance and the dialysance at at least one of a blood flow rate Qb(t), a dialysis fluid flow rate Qd(t), and an ultrafiltration rate Qf(t), on the basis of at least one of the clearance and the dialysance established at the at least one of a predetermined blood flow rate Qb, a predetermined dialysis fluid flow rate Qd, and a predetermined ultrafiltration rate Qf as recited in amended claim 7, but merely describes a control unit 26 which calculates the performance of the artificial kidney, i.e., dialysance, clearance, according to, inter alia, the flow rates of the blood QB and of the dialysis liquid QD. Furthermore, to the extent that Bene describes a device that determines a "measured rate of ultrafiltration"", Bene does not disclose a computer unit which determines at least one of the clearance and the dialysance at an ultrafiltration rate Qf(t), on the basis of at least one of the clearance and the dialysance established at the predetermined ultrafiltration rate Qf, as recited in amended claim 7

To anticipate a claim, each and every element as set forth in the claim must be found in a single prior art reference. Verdegaal Bros. v. Union Oil Co. of

Calif., 814 F.2d 628, 631, 2 U.S.P.Q.2d 1051, 1053 (Fed. Cir. 1987). Furthermore, "[t]he identical invention must be shown in as complete detail as is contained in the . . . claim." Richardson v. Suzuki Motor Co., 868 F.2d 1226, 1236, 9 U.S.P.Q.2d 1913, 1920 (Fed. Cir. 1989). That is, the prior art must describe the elements arranged as required by the claims. In re Bond, 910 F.2d 831, 15 U.S.P.Q.2d 1566 (Fed. Cir. 1990). As more fully set forth above, it is respectfully submitted that Bene does not disclose, or even suggest, that a means for determining at least one of a clearance and a dialysance is a computer unit which determines at least one of the clearance and the dialysance at at least one of a blood flow rate Qb(t), a dialysis fluid flow rate Qd(t), and an ultrafiltration rate Qf(t), on the basis of at least one of the clearance and the dialysance established at the at least one of a predetermined blood flow rate Qb, a predetermined dialysis fluid flow rate Qd, and a predetermined ultrafiltration rate Qf as recited in amended claim 7.

Additionally, to reject a claim under 35 U.S.C. § 102, the Examiner must demonstrate that each and every claim limitation is contained in a single prior art reference. See, Scripps Clinic & Research Foundation v. Genentech, Inc., 18 U.S.P.Q.2d 1001, 1010 (Fed. Cir. 1991). Still further, not only must each of the claim limitations be identically disclosed, an anticipatory reference must also enable a person having ordinary skill in the art to practice the claimed invention, namely the inventions of the rejected claims, as discussed above. See, Akzo, N.V. v. U.S.I.T.C., 1 U.S.P.Q.2d 1241, 1245 (Fed. Cir. 1986). In particular, it is respectfully submitted that, at least for the reasons discussed above, the reference relied upon would not enable a person having ordinary skill in the art to practice the inventions of the rejected claims, as discussed above. Also, to the extent that the Examiner is relying on the doctrine of inherency, the Examiner must provide a "basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristics necessarily flows from the teachings of the applied art." See M.P.E.P. § 2112; emphasis in original; and see, Ex parte Levy, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). Thus, the M.P.E.P. and the case law make clear that simply because a certain result or characteristic may occur in the prior art does not establish the inherency of that result or characteristic. Accordingly, the anticipation rejection as to the rejected claims must necessarily fail for the foregoing reasons.

In summary, it is respectfully submitted that Bene does not anticipate claim 7.

As for claims 8, 12 and 13, which depend from claim 7 and therefore include all of the limitations of claim 7, it is respectfully submitted that Bene does not anticipate these dependent claims for at least the same reasons given above in support of the patentability of claim 7.

VII. Rejection of Claims 9 to 11 Under 35 U.S.C. § 103(a)

Claims 9 to 11 were rejected under 35 U.S.C. § 103(a) as unpatentable over Bene. It is respectfully submitted that Bene does not render obvious claims 9 to 11 for the following reasons.

The Office Action contends that "Bene disclosed the invention substantially as claimed," Office Action at p. 7, but admits that "Bene ... fails to disclose specifically that the computer calculates a diffusive component D1, effective blood flow Qe (claim 9), the diffusive dialysance D(Qd(t) for any flow rate Qd(t) (claim 10), and the sum of the diffusive and convective dialysance k(Qd(t), Qe, Of(t) or the clearance from the diffusive dialysance D(Qd(t), Qe(t) according to their respective equations set forth in their respective claims." Office Action at p. 8. However, the Office Action contends that "since the computing and control unit of Bene computes values using formulas to calculate the dialysance based on values received by other monitoring devices (for example the sensors), it clearly uses programmable software to perform the mathematical calculations [and that] the computing and control unit of Bene is clearly capable of being programmed with the required equations such that the control unit can calculate the diffusive component D1, effective blood flow Qe (claim 9), the diffusive dialysance D(Qd(t) for any flow rate Qd(t) (claim 10), and the sum of the diffusive and convective dialysance k(Qd(t), Qe, Of(t) or the clearance from the diffusive dialysance D(Qd(t), Qe(t)." Office Action at p. 8. Thus, the Office Action concludes that "[i]t would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the computing and control unit of Bene to store desired equations to calculate diffusive component D1, effective blood flow Qe (claim (), the diffusive dialysance D(Qd(t) for any flow rate Qd(t) claim 10), and the sum of the diffusive and convective dialysance k(Qd(t), Qe, Of(t) or the clearance from the diffusive dialysance D(Qd(t),

since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art." Office Action at p. 8.

As stated above, it is respectfully submitted that Bene does not disclose, or even suggest, all of the limitations recited in claim 7. For example, it is respectfully submitted that Bene does not disclose, or even suggest, that a means for determining at least one of a clearance and a dialysance is a computer unit which determines at least one of the clearance and the dialysance at at least one of a blood flow rate Qb(t), a dialysis fluid flow rate Qd(t), and an ultrafiltration rate Qf(t), on the basis of at least one of the clearance and the dialysance established at the at least one of a predetermined blood flow rate Qb, a predetermined dialysis fluid flow rate Qd, and a predetermined ultrafiltration rate Qf as recited in amended claim 7.

In rejecting a claim under 35 U.S.C. § 103(a), the Examiner bears the initial burden of presenting a prima facie case of obviousness. In re Rijckaert, 9 F.3d 1531, 1532, 28 U.S.P.Q.2d 1955, 1956 (Fed. Cir. 1993). To establish prima facie obviousness, three criteria must be satisfied. First, there must be some suggestion or motivation to modify or combine reference teachings. In re Fine, 837 F.2d 1071, 5 U.S.P.Q.2d 1596 (Fed. Cir. 1988). This teaching or suggestion to make the claimed combination must be found in the prior art and not based on the application disclosure. In re Vaeck, 947 F.2d 488, 20 U.S.P.Q.2d 1438 (Fed. Cir. 1991). Second, there must be a reasonable expectation of success. In re Merck & Co., Inc., 800 F.2d 1091, 231 U.S.P.Q. 375 (Fed. Cir. 1986). Third, the prior art reference(s) must teach or suggest all of the claim limitations. In re Royka, 490 F.2d 981, 180 U.S.P.Q. 580 (C.C.P.A. 1974). As indicated above, Bene does not disclose, or even suggest, all of the limitations recited in claim 7.

Moreover, it is respectfully submitted that the cases of In re Fine, supra, and In re Jones, 21 U.S.P.Q.2d 1941 (Fed. Cir. 1992), make plain that the Office Action's generalized assertions that it would have been obvious to modify or combine the reference do not properly support a § 103 rejection. It is respectfully submitted that those cases make plain that the Office Action reflects a subjective "obvious to try" standard, and therefore does not reflect the proper evidence to support an obviousness rejection based on the reference relied upon. In particular, the Court in the case of In re Fine stated that:

> The PTO has the burden under section 103 to establish a *prima facie* case of obviousness. It can satisfy this burden only by showing some objective teaching in the prior art or that knowledge generally available to one of ordinary skill in the art would lead that individual to combine the relevant teachings of the references. This it has not done. . . .
>
> **Instead, the Examiner relies on hindsight in reaching his obviousness determination. . . . One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.**

In re Fine, 5 U.S.P.Q.2d at 1598 to 1600 (citations omitted; italics in original; emphasis added). Likewise, the Court in the case of In re Jones stated that:

> Before the PTO may combine the disclosures of two or more prior art references in order to establish *prima facie* obviousness, there must be some suggestion for doing so, found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. . . .
>
> **Conspicuously missing from this record is any evidence, other than the PTO's speculation (if it be called evidence) that one of ordinary skill . . . would have been motivated to make the modifications . . . necessary to arrive at the claimed [invention].**

In re Jones, 21 U.S.P.Q.2d at 1943, 1944 (citations omitted; italics in original).

That is exactly the case here since it is believed and respectfully submitted that the present Office Action offers no evidence whatsoever, but only conclusory hindsight, reconstruction and speculation, which these cases have indicated does not constitute evidence that will support a proper obviousness finding. Unsupported assertions are not evidence as to why a person having ordinary skill in the art would be motivated to modify or combine reference to provide the claimed subject matter of the claims to address the problems met thereby. Accordingly, the Office must provide proper evidence of a motivation for modifying or combining the references to provide the claimed subject matter.

More recently, the Federal Circuit in the case of In re Kotzab has made plain that even if a claim concerns a "technologically simple concept" -- which is not the case here -- there still must be some finding as to the "specific understanding or

principle within the knowledge of a skilled artisan" that would motivate a person having no knowledge of the claimed subject matter to "make the combination in the manner claimed," stating that:

> In this case, the Examiner and the Board fell into the hindsight trap. The idea of a single sensor controlling multiple valves, as opposed to multiple sensors controlling multiple valves, is a technologically simple concept. With this simple concept in mind, the Patent and Trademark Office found prior art statements that in the abstract appeared to suggest the claimed limitation. But, there was no finding as to the specific understanding or principle within the knowledge of a skilled artisan that would have motivated one with no knowledge of Kotzab's invention to make the combination in the manner claimed. In light of our holding of the absence of a motivation to combine the teachings in Evans, we conclude that the Board did not make out a proper prima facie case of obviousness in rejecting [the] claims . . . under 35 U.S.C. Section 103(a) over Evans.

In re Kotzab, 55 U.S.P.Q.2d 1313, 1318 (Fed. Cir. 2000) (emphasis added). Again, it is believed that there have been no such findings.

In summary, it is respectfully submitted that Bene does not disclose, or even suggest, all of the limitations recited in claim 7. As for claims 9 to 11, each of which ultimately depend from claim 7 and therefore include all of the limitations of claim 7, it is respectfully submitted that Bene does not render unpatentable these dependent claims for at least the same reasons given above in support of the patentability of claim 7. In re Fine, supra (any claim that depends from a non-obvious independent claim is non-obvious).

VIII. Conclusion

Attached hereto is a marked-up version of the changes made to the Specification and claims by the current Amendment. The attached page is captioned "**Version with Markings to Show Changes Made**."

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

KENYON & KENYON

Dated: February 25, 2003 By: _____

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PATENT TRADEMARK OFFICE

Version with Markings to Show Changes Made

IN THE CLAIMS:

Claim 7 has been amended without prejudice as follows:

7. (Amended) A dialysis machine, comprising:

a dialyzer;

a semipermeable membrane dividing the dialyzer into a blood chamber and a dialysis fluid chamber, the blood chamber having an inlet and an outlet, and the dialysis fluid chamber having an inlet and an outlet;

an arterial blood line connected to the inlet of the blood chamber;

a venous blood line connected to the outlet of the blood chamber;

a dialysis fluid inlet line connected to the inlet of the dialysis fluid chamber;

a dialysis fluid outlet line connected to the outlet of the dialysis fluid chamber;

a first device [rate determining means] for determining at least one of a blood flow rate Qb through the blood chamber, a dialysis fluid flow rate Qd through the dialysis fluid chamber, and an ultrafiltration rate Qf;

means for determining at least one of a clearance and a dialysance during a dialysis treatment, at the at least one of the blood flow rate Qb, the dialysis fluid flow rate Qd, and the ultrafiltration rate Qf determined by the first device, wherein the means for determining at least one of a clearance and a dialysance is a computer unit which determines at least one of the clearance and the dialysance at the at least one of a blood flow rate Qb(t), a dialysis fluid flow rate Qd(t), and an ultrafiltration rate Qf(t), on the basis of at least one of a clearance K1 and a dialysance established at the at least one of a predetermined blood flow rate Qb1, a predetermined dialysis fluid flow rate Qd1, and a predetermined ultrafiltration rate Qf1.

Claim 8 has been cancelled without prejudice.